

PATENT COOPERATION TREATY

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From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

26 FEB 2001

To:

Baldwin Shelston Waters
PO Box 5999
Wellesley Street, AUCKLAND
New Zealand

PCT NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
day/month/year

19 FEB 2001

Applicant's or agent's file reference
JM/503288-142

IMPORTANT NOTIFICATION

International Application No.
PCT/NZ99/00228

International Filing Date
24 December 1999

Priority Date
24 December 1998

Applicant
AUCKLAND UNISERVICES LIMITED et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JM/503288-142	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/NZ99/00228	International Filing Date (<i>day/month/year</i>) 24 December 1999	Priority Date (<i>day/month/year</i>) 24 December 1998
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 14/315, 16/12; C07H 19/00; C12N 1/20; C12Q 1/68; A61K 35/74, 39/09		
Applicant AUCKLAND UNISERVICES LIMITED et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheet(s).
3. This report contains indications relating to the following items:
- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input checked="" type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 21 July 2000	Date of completion of the report 14 February 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  IAN DOWD Telephone No. (02) 6283 2273

I. Basis of the report

1. With regard to the elements of the international application:*
- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of
2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☒ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-30	YES
	Claims	NO
Inventive step (IS)	Claims 1-30	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-30	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 Journal of Experimental medicine (1999) 189(1), 89-101
"Identification and characterization of novel superantigens from *Streptococcus pyogenes*" Proft, T et al
- D2 Database GenPept, Accession No. CAB51744, Authors: Gerlach, D, Wagner, M, Fleischer, B, Schmidt, KH, Vettermann, S, Reichardt, W.
Submitted 29 July 1999.
- D3 Database GenPept, Accession No. CAB51332, Authors: Gerlach, D, Wagner, M, Fleischer, B, Schmidt, KH, Vettermann, S, Reichardt, W.
Submitted 19 July 1999.
- D4 Database GenPept, Accession No. CAB51142, Authors: Gerlach, D, Wagner, M, Fleischer, B, Schmidt, KH, Vettermann, S, Reichardt, W.
Submitted 19 July 1999.
- D5 Infection and Immunity (1998) 66(7), 3337-3348
"Identification and Characterization of Staphylococcal Enterotoxin Types G and I from *Staphylococcus aureus*"
Munson, SH et al
- D6 Molecular Microbiology (1998) 29(2), 527-543
"The gene for toxic shock toxin is carried by a family of mobile pathogenicity islands in *staphylococcus aureus*". Lindsay, JA et al.
- D7 Infection and Immunity (1998) 56(9), 2518-2520
"Nucleotide Sequence of Streptococcal Pyrogenic Exotoxin Type C"
Goshorn, SC and Schlievert, PM

Continued on Supplemental Sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/NZ99/00228

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
P,X WO 99/27889	10 June 1999	1 December 1998	2 December 1997

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non- written disclosure (day/month/year)
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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D8 Database Swiss-Prot, Accession No. SPEC_STRPY
& Infection and Immunity (1998) 56(9), 2518-2520
& Infection and Immunity (1992) 60: 3513-3517
& Nat Struct Biol (1997) 4: 635-643

D9 Database GenPept, Accession No. AAB 59091,
& Infection and Immunity (1998) 56(9), 2518-2520
& Infection and Immunity (1992) 60: 3513-3517

D10 WO 99/27889 (10 June 1999) IDAHO RESEARCH FOUNDATION INC

Documents D1, D2, D3, and D4 have an earlier publication date than the priority date claimed in the international application. The International Preliminary Searching Authority was unable to view the priority document of the international application to ascertain priority entitlement. However, this report is established on the assumption that the application enjoys the earlier date.

Documents D1, D2, D3, and D4 are excluded for the purposes of considering Novelty or Inventive Step due to the assumption explained above. However, if a priority issue with the application, eg the application is not entitled to the earlier priority, arises then these documents would become relevant and should be considered for the purposes of novelty and inventive step.

With regard to the document D10 listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

NOVELTY and INVENTIVE STEP

Documents D5 and D6 disclose polypeptide sequence listings that have 35% and 34%, respectively, identity to sequence ID No. 2 of the application. Documents D7, D8 and D9 disclose polypeptide sequence listings that have 55.5%, 55.5% and 56%, respectively, identity to sequence ID No. 8 of the application. The description of the invention in the application does not give an indication of the percentage identity the claimed polypeptide sequences need as a minimum to retain functional equivalence. Therefore bearing this in mind, the documents cited herein are potentially novelty destroying if the above identified identity affords functional equivalence.

However, the applicant has argued that the citations identified disclose sequences of other known bacterial superantigens having different functional properties. The sequences, they argue, encode for proteins with significantly different functional properties, host specificities and potential disease associations. Given these arguments, this Preliminary Examining Authority acknowledges novelty and inventive step for the claims relating to sequence ID No.s 2 and 8. Consequently, sequence ID No.s 1 and 7 relating to the nucleotide of Sequence ID No.s 2 and 8, respectively, are also novel and inventive.

Continued on Supplemental Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

Documents D5, D6, D7, D8, and D9 do not disclose Sequence ID No.s 4 or 6 relating to polypeptide. Therefore claims relating to these sequence ID's are novel. Furthermore, documents D5, D6, D6, D8, and D9 do not lead a person skilled in the art to arrive at Sequence ID No.s 4 or 6. Therefore claims relating to these sequence ID No.s 4 or 6 are non-obvious and possess an inventive step. Consequently, sequence ID No.s 3 and 5 relating to the nucleotide of Sequence ID No.s 4 and 6, respectively, are also novel and inventive.

INDUSTRIAL APPLICABILITY

Rule 67 lists the subject matter which under Article 34(4)(a)(i) an international preliminary examination is not required to be carried out. At item (iv) it specifies methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods, as such matter. However the agreement between WIPO and Australia further qualifies this by excepting from exclusion any subject matter which is examined under national grant procedures. Claim 30 has nonetheless been considered because the identified subject matter does not contravene Australian law. Consequently, claims 1-30 relate to matter which is considered to meet the requirement of Article 33(4).